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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,567	09/05/2006	Joern Borgert	DE 040071	7279

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P.O. BOX 3001
BRIARCLIFF MANOR, NY 10510

EXAMINER

GUPTA, VANI

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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12/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,567	BORGERT ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/22/09</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. ***Claims 1, 2, and 5 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usami et al. (US 6,610,046 B1) in view of Haim et al. (US 2002/0013615 A1).***

Regarding claims 1 and 2, Usami et al. discloses a catheter apparatus for the therapeutic embolization of aneurysm, the catheter apparatus comprising:

- a. a catheter configured to inject a therapeutic drug into a region of interest by means of a pump, where the pump is configured to controllably supply therapeutic drug to the catheter (*col. 3, line 54 – col. 4, line 15; col. 26, ll. 3 - 27*).

However, Usami et al. does not suggest Claim 1 with respect to the features involving the active locator and monitor.

Nonetheless, Hiam et al. also suggests a catheter configured to inject a therapeutic drug into a region of interest by means of a pump, where the pump is configured to controllably supply therapeutic drug to the catheter (*paragraphs [0020, [0038, [0109]]*). Hiam et al. also teaches that the method of controlling the supply of a plugging material to a catheter comprising a step of determining the position and/or orientation of the catheter via an active locator fitted thereon (*paragraphs [0111 – 0113]; and **fig. 3***). Details include:

- b. an *active locator* comprising a magnetic field sensor, configured to determine spatial position and orientation of the catheter (*paragraph [0021], first sentence; paragraph [0023]*). A locating device (*steering mechanism*) is assigned to the catheter that works in connection with the active locator, and is capable of determining the position and orientation of the catheter (*paragraph [0021]*). In fact, as is known in the art, as the steering mechanism steers the catheter, determining the spatial position and orientation of the catheter would be inherent to the steering process.; and
- c. a monitor connected to the active locator and the pump, wherein the monitor is configured to detect emergence of the catheter from a region of interest (ROI) during the injection of the drug into the ROI, and configured to stop the supply of the drug in response to the detected emergence (*para. [0028]*). Hiam et al. also explains the importance of proper contact between the catheter and region of interest (*para. [0023]*); and dispensing an appropriate amount of drug or dispense drug to an “appropriate depth” (*para. [0018]*). Means for ensuring proper contact is also provided (*para. [0071]*).

Accordingly, Usami et al. in view of Haim et al. teaches monitoring the position and orientation of the catheter in the aneurysm; and stopping the administration of the drug if the catheter emerges from the aneurysm.

It would have been prima facie obvious to modify Usami et al. with Haim et al. to include a step of stopping the supply of the plugging material to a catheter if emergence of the catheter from the aneurysm is detected to avoid “deleterious effects” such as “possible systemic toxicity” (*paragraph [0112]*).

Regarding claims 5 and 6, Usami et al. in view of Haim et al. discloses a catheter, a pump device and an electromagnetic locating device, and monitoring capabilities for detecting emergence of the catheter from the region of interest during injection of the drug into the region of interest, and thereupon stopping the supply of the drug (please see rejections of claims 1 and 2). There is control circuitry containing storage space for storing a “road map;” and is designed to record measured position of the locator using the road map. Applicant should note that control circuitry comprises a computer, which would inherently comprise a storage device capable of storing any type of information, including medical image data. (*paragraphs [0054 – 0075] and [0108 – 0111]*).

Regarding Claim 7, Haim et al. discloses, via incorporation of **US 5,568,809** (*paragraph [0105]*), that the apparatus of Claim 5 further comprises an imaging device, such as X-ray (*see US 5,568,809: col. 3, lines 43 – 60 and col. 5, lines 31 – 38*).

Regarding Claim 8, please see rejection of claims 5 and 6; method for performing intended feature is accomplished by electromagnetic active locator.

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Regarding Claim 9, Applicant should note that it would be inherent matter of design choice that if Haim et al. discloses a locating device that works in conjunction with a magnetic field sensor device, then the locating device would comprise capabilities for generating an electromagnetic field for the magnetic field sensor to sense.

Regarding Claim 10, Usami et al teaches that the plugging material can comprise a curable polymer material (*col. 26, line 8*).

Regarding Claim 11, please refer to rejections of claims 1 and 5.

Regarding Claim 12, Haim et al. teaches that the position of the locator is recorded using a road map generated prior to the step of positioning of the catheter (*paragraph [0110], see last sentence*).

Regarding Claim 13, Haim et al. teaches, via incorporation of **US 5,568,809** (*mentioned in paragraph [0105]*), that the catheter and the aneurysm are imaged together at the start of embolization, preferably by means of X-rays or with administration of a contrast agent (**US 5,568,809: col. 3, line 65 – col. 4, line 24**).

Regarding Claim 14, Usami et al. in view of Haim et al. teaches that the navigation of the catheter in the vascular system is assisted by determining the position of the active locator, as discussed in the rejection of Claim 11.

Response to Arguments

1. Applicant's arguments filed July 9, 2009 have been fully considered are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Usami et al. (US Patent 6,610,046 B1).

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With respect to Claims 1, 2, 5, and 6 – 11, Usami et al. provides teachings for specifically using catheter to inject a filler material to plug an aneurysm (*col. 3, line 54 – col. 4, line 15; col. 26, ll. 3 - 27*). Please refer to above rejections for more details. Therefore, Usami et al. in view of Hiam et al. provides suggestions or teachings for the features of the present invention. Please refer to above rejections for more details.

Applicant argues that Haim et al. does not suggest or teach a monitor connected to the active locator and the pump, wherein the monitor is configured to detect emergence of the catheter from the aneurysm during the injection of the filling material into the aneurysm, and configured to stop the supply of the filling material in response to the detected emergence.

Examiner respectfully disagrees. Haim et al. discusses the importance of proper contact between the catheter and region of interest (*para. [0023]*); and dispensing an appropriate amount of drug or dispense drug to an “appropriate depth” (*para. [0018]*). Means for ensuring proper contact is also provided (*para. [0071]*). If there isn’t proper contact between the catheter and region of interest, drug administration is automatically disabled (*para. [0028]*).

Arguments against Bell are moot in light of new grounds of rejection and above response.

Conclusion and Communication

This rejection is ***NON-FINAL***.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./

Examiner, Art Unit 3768

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768